

Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The rejection proffers that the specification does not describe the "impregnated conjugate" in such a way as to clearly identify the different components of such a conjugate". First, it is noted that claim 15 requires that the impregnated conjugate comprises "a first bioaffine binding partner . . . and a first detectable label." Next, the Examiner's attention is directed to page 9, first paragraph where the specification teaches, "the conjugates can be impregnated in the suitable matrix material." In addition, the term "impregnated conjugate" is supported at page 1 paragraph 1 and page 3 paragraph 5. Accordingly, the term "an impregnated conjugate" is believed to be sufficiently definite for purposes of 35 USC 112.

The rejection further proffers that it is unclear where the second detectable label is located. Claim 15 requires that the universal conjugate comprises "a second bioaffine binding partner . . . and a second detectable label". The location of the universal conjugate is claimed as being "upstream of the zone containing immobilized analyte or analyte analogue". Accordingly, the location of the second detectable label is believed to be sufficiently definite for purposes of 35 USC 112, second paragraph.

Regarding claim 20, antecedent support for the term "the second bioaffine binding partner" is found in claim 15, lines 14-15. Claim 20 further defines the second bioaffine binding partner as being "an antibody to digoxigenin or digoxin". Accordingly, claim 20 is believed to have adequate antecedent support.

Claims 16-26 depend from claim 15. The claims are believed to be sufficiently definite for purposes of 35 USC 112, second paragraph. Accordingly, reconsideration of the rejection leading to its withdrawal is respectfully requested.

Claims 15-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Decker et al. (US 4,230,683). The rejection proffers that it would have been obvious . . . to modify the device of Fitzpatrick et al. by using the hapten-labeled method of Decker et al.

Fitzpatrick et al. discloses an assay whereby sample is applied to move through three zones. A mobilizable receptor capable of binding to the analyte is present in the first zone. A trap for unbound receptor, consisting of immobilized ligand, is present in

the second zone. Mobilization and migration of the receptor can be detected in the third zone.

The Examiner's statement that Fitzpatrick et al. fails to teach a universal conjugate is acknowledged. Further, it is submitted that the teachings of Fitzpatrick et al. actually lead away from the element of the claimed invention. Unlike the required "impregnated conjugate" required by claim 15, Fitzpatrick et al. teaches that its receptor is applied to the membrane sheet so that said sheet is coated. See, Column 11, lines 36-41 and Column 12, lines 40-51. One of skill in the art, based upon the teachings of Fitzpatrick et al. would be lead towards a coated receptor and therefore away from the an element that comprises an impregnated conjugate, in accordance with claim 15. Fitzpatrick et al. fails to provide any motivation to form an element with an impregnated conjugate, let alone an impregnated conjugate located upstream of the zone containing immobilized analyte or analyte analogue that comprises a first bioaffine binding partner and a first detectable label, as required by claim 15.

In addition, it is respectfully submitted that not only does the secondary reference to Decker et al. fail to cure the above-stated inadequacies of Fitzpatrick et al., but when considered for all that it teaches, leads away from the presently claimed invention. Decker et al. requires that its test sample be bound to a solid support. See, for example, Col. 1 lines 56-63, Col. 2 lines 4-10 and 59-66, and Col. 3 lines 28-32 where an assay for determining antigen or antibody from a test sample bound to a solid support is taught.

In contrast, the present invention requires a sample application zone and a detection zone located downstream from the sample application zone. Due to the differences in its assay methods as well as its failure to disclose or suggest an element that comprises an impregnated conjugate, it is submitted that Decker et al. cannot be said to provide suggestion or motivation to modify Fitzpatrick et al. to meet the requirements of claim 15.

In light of the specific teaching of Fitzpatrick et al. of a coated reagent and Decker et al. of an assay from a bound test sample, it is respectfully maintained that Fitzpatrick et al. and Decker et al. when taken as a whole, fail either alone or in combination to disclose or suggest an element comprising "a sample application zone, a detection zone . . . a zone containing immobilized analyte or analyte analogue . . . a material that enables liquid

transport between the zones, an impregnated conjugate. . . which can be detached by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule, and a universal conjugate . . . which can be detached by liquid and comprises a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label”, as required by claim 15. Claims 16-17 and 20-23 depend from claim 15.

It is respectfully submitted that the differences between the claimed invention and the cited art are such that Applicant’s invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

Claims 18, 19, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al. in view of Decker et al. as applied to claims 15-17 and 20-23 above, and further in view of Bernstein et al (US 5,824,268). Claims 18, 19 and 24-26 depend from independent claim 15.

Bernstein et al. discloses a test strip having three zones – a reaction zone, a sample zone, and a detection zone. The Examiner’s statement that Fitzpatrick et al. and Decker et al. fail to teach an elution agent application zone located upstream of the sample application zone is acknowledged. As discussed above, it is submitted that neither Fitzpatrick et al. nor Decker et al. either alone or in combination with one another disclose or suggest the element of claim 15.

Bernstein et al. fails to cure the above-stated inadequacies of Fitzpatrick et al. and Decker. It is therefore respectfully submitted that Bernstein cannot be said to provide suggestion or motivation to modify Fitzpatrick et al. and Decker et al. to meet the requirements of dependent claims 18, 19, and 24-26.


Accordingly, it is submitted that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

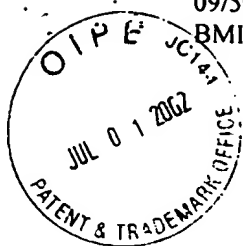
The claims as submitted herein are believed to be in condition for allowance, and

allowance of the application is respectfully requested. In addition, it is requested that any fees due be charged to Deposit Account Number 50-0877 with reference to (BMID 9941 US).

Respectfully submitted,

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Clean Version Of Replacement Claims For Entry During Prosecution Of Us  
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15. An element for the determination of an analyte in a liquid, the element comprising:
- a sample application zone,
  - a detection zone located downstream from the sample application zone;
  - a zone containing immobilized analyte or analyte analogue located between the sample application zone and the detection zone,
  - a material that enables liquid transport between the zones,
  - an impregnated conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule, and
  - a universal conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label.
16. An element as claimed in claim 15, wherein the first detectable label is digoxigenin or digoxin.
17. An element as claimed in claim 16, wherein the second bioaffine binding partner is an antibody to digoxigenin or digoxin.
18. An element as claimed in claim 16, further comprising an elution agent application zone located upstream of the sample application zone.
19. An element as claimed in claim 18, wherein the impregnated conjugate and the universal conjugate are located between the elution agent application zone and the sample application zone.
20. An element as claimed in claim 15, wherein the second bioaffine binding partner is an antibody to digoxigenin or digoxin.
21. An element as claimed in claim 15, wherein the second detectable label is metal particles or latex particles.

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22. An element as claimed in claim 21, wherein the second detectable label is gold particles.

23. An element as claimed in claim 15, wherein the impregnated conjugate and the universal conjugate are located in the sample application zone.

24. An element as claimed in claim 15, further comprising an elution agent application zone located upstream of the sample application zone.

25. An element as claimed in claim 24, wherein the impregnated conjugate and the universal conjugate are located between the elution agent application zone and the sample application zone.

26. An element as claimed in claim 24, wherein the impregnated conjugate and the universal conjugate are located in the sample application zone.